

## **REMARKS**

### **Status of Claims**

Claims 15-31 are pending in this application. Claims 23 and 27 have been amended herewith to further clarify the subject matter being claimed. No new subject matter or new issue is introduced by the claim amendments. Based on the Remarks below, reconsideration and allowance are respectfully requested.

### **Objection to the Information Disclosure Statement**

The Examiner has alleged that the information disclosure statement filed 09/08/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Accordingly, the Examiner states that the information disclosure statement as filed has been placed in the application file, but the information referred to therein has not been considered. Applicants respectfully traverse this objection.

The Examiner's attention is directed to 37 CFR 1.98(d), that provides EXCEPTIONS to the requirement that a copy of the information must be provided. The 37 CFR 1.98(d) expressly states that a copy of any patent, publication pending U.S. application, or other information listed in an information disclosure statement is NOT required to be provided if: (a) the information was previously cited by or submitted to, the Office in a prior application, provided that the prior application is properly identified in the IDS and is relied on for an earlier filing date under 35 U.S.C. 120; and (b) the IDS submitted in the earlier application complies with 37 CFR 1.98 (a)-(c). If both of these conditions are met, the examiner will consider the information previously cited or submitted to the Office and considered by the Office in a prior application relied on under 35 U.S.C. 120. Further, the 37 CFR 1.98(d) provides that if the information cited or submitted in the prior application was not in English, a concise explanation of the relevance of the information to the new application is NOT required unless the relevance of the information differs from its relevance as explained in the prior application.

Here, based on the 37 CFR 1.98(d), Applicants do not need to submit copies of the references listed in the IDS received on 09/08/2005, and the Examiner should consider these references because, first, these references have been previously submitted to and considered by the Office in prior applications, which have been properly identified in the IDS. For instance, the IDS as received on 09/08/2005 expressly states that the references listed have been disclosed and/or made of record in the prosecution of prior applications leading to U.S. Patent Nos. 6,339,718 ("the '718 patent") and 6,643,537 ("the '537 patent"); and U.S. Application Serial Nos. 09/941,224 ("the '224 application"), 10/309,413 ("the '413 application") and 10/757,348 ("the '348 application"), so that copies of these references can be found in these application files.

Second, the current pending application relies on the above properly identified prior applications for an earlier filing date under 35 U.S.C. 120. For instance, the current pending application is a continuation application of the '537 patent, which is a continuation-in-part application of the '718 patent. The '348 application is a reissue application of the '718 patent; the '224 application is a continuation application of the '718 patent, and the '413 application is the continuation-in-part application.

Third, the IDSs submitted in the above-identified earlier applications that the current pending application relies on comply with 37 CFR 1.98 (a)-(c). Furthermore, Applicants have realized that the Examiner has initialed most of the references listed in the IDS, indicating that these references have been considered by the Examiner. However, the Examiner has also drawn lines through several references, indicating these references have NOT been considered by the Examiner. For the reasons stated above, Applicants respectfully submitted that the Examiner had made an error by excluding these references for consideration and requiring copies of these references because these references had been properly submitted to and considered by the Office in the earlier applications, e.g. the applications leading to the '718 patent and the '537 patent, that the current application relies on for early filing date under 35 U.S.C. 120.

Nevertheless, for the effort of advance prosecution, Applicants respectfully submit herewith copies of references that the Examiner requested and a new Information Disclosure Statement and Form PTO 1449. Accordingly, Applicants respectfully submit that the Examiner withdraw the objection and consider all the references listed in the IDS.

### **Rejection of Claims under 35 U.S.C. § 112**

Claim 27 was rejected under 35 U.S.C. § 112, for lack of a sufficient antecedent basis for the limitation “the corresponding fluid container” in the claim. Applicants have amended Claim 27 by replacing the word “the” with the word “a” rendering the rejection moot.

### **Double-Patenting Rejection**

The Examiner has rejected Claims 15-31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-11, 20-25, 27, 34, and 35 of the U.S. Patent No. 6,643,537 (“the ‘537 patent”) in view of Cain, U.S. Patent No. 5,984,368 (“the ‘368 patent”). Applicants respectfully submit that the attached terminal disclaimer over the ‘537 patent overcomes this double patent rejection. Moreover, Applicants also respectfully submit that the double-patenting rejection in view of the ‘368 patent is improper because the ‘368 patent is not claiming a substantially identical invention and it is not commonly owned with the current pending application, as well as the ‘537 patent. Accordingly, Applicants respectfully submit that the double-patenting rejection in view of the ‘368 patent be withdrawn.

### **Rejection of Claims under 35 U.S.C. § 102**

Claims 15-17, 19-26, and 31 were rejected under 35 U.S.C. § 102(e) as being anticipated by Engleson et al. (U.S. Patent No. 6,671,563). Specifically, the Examiner has alleged that Engleson et al. discloses a fluid injection system in which multiple fluid containers are connected to pumps, which serves as the drive mechanism; each fluid container is operably associated with a drive mechanism, which are controlled by the bedside CPU, or controller; the system includes visual displays, touch screens, and the illumination device that is interpreted to be the bedside display, each with a plurality of elements, such as graphics and text, which may be color-coded; and an alarm condition displayed on the video display, which flashes red to “attract attention to the alert.” (See pages 4-5 of the Office Action). Applicants respectfully traverse the rejection.

It should be pointed out that Engleson et al. does not teach and suggest each and every elements as claimed in the application. For instance, Engleson et al. does not teach a fluid injection system that comprises an injector comprising two drive mechanisms and two illumination devices, respectively; two fluid containers that contain two fluids, respectively, and

which are operably associated with the two drive mechanisms, respectively; and a control device that is operably associated with the drive mechanism, and comprises a computer screen having two elements affiliated with the two illumination devices, respectively, and wherein the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid.

Engleson et al., on the other hand, discloses and claims a system for collecting data and managing patient care. Although Engleson's system includes visual displays and touch screens for interfacing with the system and allow for monitoring and adjusting the infusion pump by providing and evaluating status information of the pump on the display, and a color-coded illumination device for indication of the status and schedule of each drug administration for each patient or for a red patient alert, Engleson's system does not include an injection system including dual drive mechanisms, e.g., dual-syringe arrangement with two motors, with dual illumination devices, and a control device having computer touch screen and display with dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid. Therefore, Engleson et al. does not teach or suggest first and second different light colors corresponding to each of the first and second different fluids in the dual-syringe arrangement of the present injection system.

Because Engleson et al. does not teach and suggest each and every element of the claimed invention, the claims in the current invention are not anticipated by Engleson et al. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

### **Rejection of Claims under 35 U.S.C. § 103**

A. Claims 18 and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Engleson et al. in view of Uber et al. (U.S. Patent No. 5,494,036). Specifically, the Examiner has alleged that Engleson et al. uses a pump as an infusion system and does not disclose the use of a syringe having a plunger and a piston adapted to engage the plunger of the syringe. Uber et al., however, was alleged to disclose a contrast infusion system in which two motors are used to

engage the plungers of two syringes inside the injector unit. Accordingly, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Engleson et al. with the disclosure of Uber et al. and use a syringe system in place of the pump infusion system. Applicants respectfully traverse the rejection.

It should be pointed out that Claims 18 and 28 are dependent claims depending upon independent Claims 15 and 23, respectively, and further claim a feature of fluid container as being a syringe with a plunger and a piston. As discussed before, Engleson's system does not provide an injection system including dual drive mechanisms, e.g., dual-syringe arrangement with two motors, with dual illumination devices, and a control device having computer touch screen and display with dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid, as claimed in the independent Claims 15 and 23.

Such deficiency is not cured by Uber et al. even though Uber et al. teaches a patient infusion system for use with MRI having dual-syringe arrangement. Uber et al. does not teach or suggest dual-syringes with dual-illumination devices, and a control device having dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid. Therefore, Engleson et al., alone or in combination with Uber et al., does not teach or suggest a dual illumination device with first and second different light colors corresponding to each of the first and second different fluids in the dual-syringe arrangement of the present injection system. Such features provide a superior advantage for remote patient monitoring in a field where there is a great need for quick and accurate determination of which fluids are being administered to a patient.

Because neither Engleson et al. nor Uber et al., alone or in combination, suggests each and every feature of the invention as claimed, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Engleson's system with Uber's infusion

system and come up with the invention as claimed in the current application. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) over Engleson et al. in view of Uber et al. be withdrawn.

B. Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Engleson et al. in view of Niehoff (U.S. Patent No. 5,681,286). Specifically, the Examiner has alleged that Engleson et al. discloses using a flashing icon to alert a problem with the infusion pump as well as using various icons, graphics, and text to monitor the status of the infusion pump. However, Engleson et al. fails to disclose explicitly using either a flashing, on, or off condition to signify the state of the system. Niehoff teaches the use of an LED as an indicator for an infusion system in which the LED flashes when the plunger is moving, is steady when the system is locked, and would be off when the system is off. Accordingly, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system disclosed by Engleson et al. to use a flashing condition, a steady condition, and a off condition to signify the status of the injection system. Applicants respectfully traverse the rejection.

It should be pointed out that Claim 20 is a dependent claim, depending upon Claim 19 that depends on the independent Claim 15, and further claims a feature of a flashing condition, indicating various conditions, e.g., an armed state, a steady condition, or an off condition, of the system. As discussed before, Engleson's system does not provide an injection system including dual drive mechanisms, e.g., dual-syringe arrangement with two motors, with dual illumination devices, and a control device having computer touch screen and display with dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid, as claimed in the independent Claim 15.

Such deficiency is not cured by Niehoff even though Niehoff teaches an LED indicator for various conditions for an infusion system, as the Examiner noticed. Like Uber et al, Niehoff does not teach an injector system including dual-syringes with dual-illumination devices, and a control device having dual elements affiliated with the dual illumination devices so that the first

illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid.

Therefore, Engleson et al., alone or in combination with Niehoff, does not teach or suggest first and second different light colors corresponding to each of the first and second different fluids in the dual-syringe arrangement of the present injection system. Such features provide a superior advantage for remote patient monitoring in a field where there is a great need for quick and accurate determination of which fluids are being administered to a patient.

Because neither Engleson et al. nor Niehoff, alone or in combination, suggests each and every feature of the invention as claimed, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Engleson's system with Niehoff's injector and come up with the invention as claimed in the current application. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) over Engleson et al. in view of Niehoff be withdrawn.

C. Claims 27, 29, and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engleson et al. in view of Cain (U.S. Patent No. 5,984,368). Specifically, the Examiner has alleged that Engleson et al. does not disclose using the same color-coding used on the graphical display on the fluid containers themselves. However, Cain teaches that it is known in the art to match medications from a time chart to the medicine containers as well and further such charts may be "implemented as screen displays in a computer program." Accordingly, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to extend the color-coding already disclosed by Engleson et al. to the fluid containers themselves in light of the teachings of the reference by Cain to reduce the chance of confusing the fluid containers. Applicants respectfully traverse the rejection.

It should be pointed out that Claims 27, 29 and 30 are dependent claims, depending upon the method Claim 23 that is directed to a method of operating an injector system of the present invention for providing a color coding corresponding to a programmed injection protocol, and further claim a feature of corresponding multiple color codings showing on the computer screen for flashing and/or contrast phases with the same multiple color codings for the fluid containers

containing flashing and/or contrast phase medium, respectively. As discussed before, Engleson's system does not provide an injector system as claimed including dual drive mechanisms, e.g., dual-syringe arrangement with two motors, with first and second illumination devices, and a control device having computer touch screen and display with first and second elements affiliated with first and second illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid. Accordingly, Engleson's system would not be suitable to be operated for providing corresponding multiple color codings on the computer screen with the same multiple color codings for dual-fluid containers for a programmed injection protocol.

Moreover, such deficiency is not cured by Cain even though Cain teaches match medication from a time chart to the medicine containers, and the chart may be further implemented as screen displays in computer program. Cain does not teach a method for providing a color coding corresponding to a programmed injection protocol using an injector system, as claimed in the present invention. Therefore, Engleson et al., alone or in combination with Cain, does not teach or suggest first and second different light colors corresponding to each of the first and second different fluids in the dual-syringe arrangement of the present injection system. Such features provide a superior advantage for remote patient monitoring in a field where there is a great need for quick and accurate determination of which fluids are being administered to a patient.

Because neither Engleson et al. nor Cain, alone or in combination, suggests each and every feature of the invention as claimed, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Engleson's system with Cain's chart or screen displays and come up with the invention as claimed in the current application. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) over Engleson et al. in view of Cain be withdrawn.

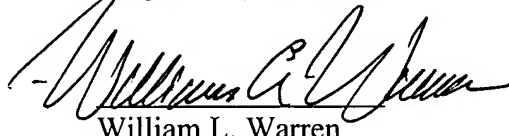


In re Application of: Zatezalo et al.  
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**Conclusions**

It is believed that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the examiner believes, for any reason, that personal communication will expedite prosecution of this application, the examiner is encouraged to call the undersigned attorney at 404-853-8081.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William L. Warren', is written over a horizontal line.

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